

PATENT COOPERATION TREATY

To:

SHRIVASTAVA Ratnesh
INTELLECTUAL PROPERTY CELL
17/B, MAHAL INDUSTRIAL ESTATE, OFF
MAHAKALI CAVES ROAD, ANDHERI (E)
400093 MUMBAI
India

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference DES₀1		Date of mailing (day/month/year) 9 March 2006 (09.03.2006)
International application No. PCT/IN 2004/000399		FOR FURTHER ACTION See paragraph 2 below
International filing date (day/month/year) 23 December 2004 (23.12.2004)	Priority Date (day/month/year) 23 December 2003 (23.12.2003)	
International Patent Classification (IPC) or both national classification and IPC A61K 31/451 (2006.01)		
Applicant SUN PHARMACEUTICAL INDUSTRIES LIMITED		

1. This opinion contains indications relating to the following items:

- ☒ Cont. No. I Basis of the opinion
- ☒ Cont. No. II Priority
- ☒ Cont. No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Cont. No. IV Lack of unity of invention
- ☒ Cont. No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Cont. No. VI Certain documents cited
- ☒ Cont. No. VII Certain defects in the international application
- ☒ Cont. No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ AT Austrian Patent Office Dresdner Straße 87, A-1200 Vienna	Authorized officer KRENN M.
Facsimile No. +43 / 1 / 534 24 / 535	Telephone No. +43 / 1 / 534 24 / 435

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

10/583842

International application No.
PCT/IN 2004/000399

Continuation No. I**Basis of the opinion****IP20 Rec'd PCT/PTO 22 JUN 2006**

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed.
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Continuation No. II**Priority**

1. The following document has not yet been furnished: copy of the earlier application whose priority has been claimed (Rules 43bis.1 and 66.7(a)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

Continuation No. III:**Non-establishment of opinion with regard to
novelty, NonInventive step and Industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an NonInventive step (to be non obvious), or to be industrially applicable have not been examined in respect of the said claims Nos. 8, 9 because the description, claims or drawings (particular elements indicated below) or said claims Nos. 8, 9 are so unclear that no meaningful opinion could be formed (specify):

Characterization of a composition by storage instructions is insufficient.

Continuation No. IV:**Lack of unity of invention**

In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has not paid additional fees.

4. Consequently, this opinion has been established in respect of the following parts of the international application: the parts relating to claims Nos. 1-3, 10, 11 and 15.
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY****International application No.
PCT/IN 2004/000399****Continuation No. V****Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or Industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 11, 15	YES
	Claims 1-3, 10	NO
Inventive step (IS)	Claims 11, 15	YES
	Claims 1-3, 10	NO
Industrial applicability (IA)	Claims 1-3, 10, 11, 15	YES
	Claims ---	NO

2. Citations and explanations:

US 2003/0194430 A1 refers to a multi-compartment capsule; preferably one compartment is filled with a H₁-antagonist, e.g. desloratadine and the other contains a radical scavenging, e.g. vitamin E.

US 2003/0118654 A1 discloses a liquid pharmaceutical formulation comprising at least one unpleasant tasting drug, e.g. descarboethoxyloratadine and an antioxidant.

The subject matter of US 2003/0031713 A1 is a bilayer solid composition wherein one layer contains desloratadine in admixture with at least one antioxidant.

CN 1415613 A describes a stable composition of desloratadine fumarate; said salt is obligatorily formed, if desloratadine and fumaric acid are not formulated separately.

As this opinion has been established on the assumption that the relevant date is the claimed priority date, the documents CN 1552324 A, US 2003/0236236 A1 and WO 2004/080461 A2, which were published within the priority term, were not considered for the present.

In respect of the above cited documents an oral formulation (claims 1-3, 10) containing desloratadine in admixture with up to 5 % of at least one anti-oxidant is neither new nor inventive. Claims 11 and 15 show both novelty and inventive step, because none of the cited documents mentions butylated hydroxyl toluene, optionally in admixture with meglumine, as anti-oxidant.

Industrial applicability is given for claims 1-3, 10, 11 and 15.

Continuation No. VI:**Certain documents cited****1. Certain published documents (Rules 43bis.1 and 70.10)**

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY****International application No.
PCT/IN 2004/000399**

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 2004/080481 A2	23.9.2004	12.3.2004	12.3.2003, 28.10.2003, 3.11.2003, 1.12.2003
US 2003/0238236 A1	25.12.2003	22.5.2003	
CN 1552324 A	8.12.2004	28.5.2003	

Continuation No. VII:**Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:
The formulation "...a pharmaceutically acceptable organic compound that provides an alkaline pH.." (claim 1) is function-orientated and should be specified.
The use of the term "about" (claim 3) in connection with numerical ranges is not allowed.

Continuation No. VIII:**Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
The term "therapeutically effective" (claim 1) is meaningless and should be therefore deleted.